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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,804	09/12/2003	Gerold Schuler	1430/16	8361

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JENKINS, WILSON, TAYLOR & HUNT, P. A.
SUITE 1200, UNIVERSITY TOWER
3100 TOWER BOULEVARD
DURHAM, NC 27707

EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,804	SCHULER ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 24-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 12, 24-32 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/30/07 has been entered.

Response to Amendment

The rejection of claims 12, 24-30 under 35 U.S.C.102 has been withdrawn in light of Applicant's amendment.

The rejection of claims 31 and 32 under 35 U.S.C. 103 has been withdrawn in light of Applicant's amendment.

Claims 12, 24-32 are rejected under 35 U.S.C.112 1st paragraph for reasons discussed below.

Claims 12, 24-32 are rejected under 35 U.S.C.103 for reasons discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 24-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 12 as amended recites the new limitation "wherein no stimulation with cytokines or dendritic cells is performed between the steps." This limitation is not supported by the specification as originally filed because the specification does not teach or disclose a method to identify, monitor and/or remove CD4+CD25+ from human blood without stimulation from cytokine or dendritic cells. The teaching on page 4, lines 25-29 is directed to a method of identify, monitor and/or remove CD4+CD25+ from human blood by using agents that specifically binds to CD4, and/or CD25, whereas the teaching on page 13, lines 5-7 discloses that the CD4+CD25+ cells may also be generated *in vitro* by repetitive stimulation with immature DC. Such teaching does not suggest a method of identify, monitor and/or remove CD4+CD25+ from human blood without stimulation from cytokine or dendritic cells. The claims after the filing date of the as-filed application, does not provide any legal basis showing that applicant is possesses the specific claimed subject matter as claimed in the new claims at the time the invention was made. Thus, this is a new matter rejection. In other words, new or amended claim which introduces a new limitation that excludes the stimulation of cytokines or DC, and which are not supported by the as-filed disclosure as a whole, violate the written description requirement. Claims 24-32 are also rejected because they depend on claim 12 and also include this limitation.

Claim Rejections - 35 USC § 103

Claims 12, 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonuleit et al. and Takahashi et al.

Jonuleit et al. disclose a method that of identify, monitor and/or remove CD4+CD25+ cells from human blood by contacting the blood with CD4 and/or CD25 and/or CTL-A4 specific antibodies (see page 1214, 2nd col., 4th paragraph, lines 1-6, and Figure 4). Jonuleit et al. further disclose that CD4+ T cells are removed from the cord blood (page 1214, 2nd col., 4th paragraph, lines 1-3). Jonuleit et al. also disclose that the purification is carried out using antibodies attached to beads (page 1214, 2nd col., 4th paragraph, last two lines). Lastly, Jonuleit et al. disclose said method wherein the cells are stimulated with dendritic cells (see page 1215, 1st paragraph, lines 2-4). Further, Jonuleit et al. disclose analyzing expression of CTL-4.

However, Jonuleit et al. does not teach that no stimulation of DC when isolating said cells.

Takahashi et al. teach CD25+CD4+ cells are isolated from lymphoid organs of mouse by using CD25 and CD4 antibodies with stimulation of cytokines and dendritic cells (see page 304, Figure 1 and legend).

It would have been obvious to one of ordinary skill in the art to develop a method of identifying, monitoring, and removing CD4+ CD25+ regulatory T cells from human blood by using ligands specifically binds to the CD4 and CD25 based on the combined teaching of Jonuleit and Takahashi et al. Jonuleit et al. teach the CD4+ cells are first isolated from cord blood and stimulated with DC and then CD25 antibody is used to purify the CD4+CD25+ population. Takahashi et al. teach that CD25+CD4+ T cells are isolated from spleen cell

suspension by using CD4 and CD25 antibody without stimulation of the cells with cytokine or dendritic cells. It is clear from the teaching of both references that T cells that are CD4+ CD25+ can be isolated from a mixed population of cells, either from blood or lymphoid tissue, by using CD4+CD25+ antibodies. Stimulation of the mixed cell population with cytokine or dendritic cell does not affect that ability of CD4 and CD25 antibody to bind to CD4 and CD25 surface antigen on such cells, thus isolation CD4+CD25+ by using CD4 and CD25 binding ligand without stimulation of cytokine or dendritic cells would yield the predictable result. Thus, it would have been obvious to one of ordinary skill in the art to identify, monitor and removing CD4+CD25+ cells from blood by using binding ligands to such surface molecules without stimulation with cytokine or dendritic cells.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER